1.1.6 510(k) Summary

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510(k) Summary

(as required by 21 CFR 807.92 (c))

Owner's Name:

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Tel: 011 44 1243 523174
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Date Summary Prepared:

May 18, 2011

Classification:

The FDA has classified: Cardiovascular Blood Flowmeter (21 CFR 870.2100 Product ProCode DPW),

Extravascular Blood Flow Probe (21 CFR 870.2120, ProCode DPT),

Patient transducer and electrode cable (including connector) (21 CFR 870.2900, ProCode DSA) as a Class II Medical Device.

Common/Usual Name:

Esophageal Doppler Monitor

Proprietary Name:

Deltex Medical CardioQ-EDM

Predicate Devices used to Demonstrate Substantial Equivalence:

Deltex Medical CardioQ – K031706

Description, including Intended Use:

The CardioQ-EDM system employs esophageal Doppler techniques using 4 MHz continuous wave ultrasound to monitor and quantify the blood flow in the descending thoracic aorta, displaying this data as a maximum velocity curve, a velocity spectrum and derived measurements. Thus, real-time information about cardiac function, in particular left ventricular flow, is displayed continuously. This is the same as for the predicate CardioQ K031706.

The CardioQ-EDM is an enhancement of the CardioQ K031706; obsolete components have been replaced and an improved/modernized user interface created, by utilizing the full capabilities of the new components.

Technology Characteristics Compared to Predicate Devices:

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM	**Deltex CardioQ, K031706**
Indications for use	The CardioQ-EDM cardiac function and fluid status monitoring system is designed to provide clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters. The CardioQ-EDM's beat-to-beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward	same, but with minor textural updates, see section 1.3
Patient population	For use in patients 59" (149 cm) or taller	same
Patient status	Anesthetized/sedated patients/awake	same
Insertion route	Oral or Nasal	Oral in K031706 Nasal use probes added later in K052989

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM	**Deltex CardioQ, K031706**
Contraindications	Intra-aortic balloon pumping	same
	Severe coarctation of the aorta	same
	Pharyngo-esophago-gastric pathology	same
	Severe bleeding diatheses	same
System design	Esophageal probe transmits and receives 4 MHz Continuous Wave Doppler (CWD) ultrasound to measure blood flow velocities in the descending thoracic aorta	same
	Signals are returned via the Patient Interface Cable (PIC) to CardioQ-EDM Monitor	same
	CardioQ-EDM Monitor processes the signal and displays it as real-time spectrum, to show the distribution of red blood cell velocities over the entire cardiac cycle	same
	Maximum velocity envelope is continuously delineated and used to calculate velocity-integral of the waveform during systole	same
	Patient age, weight & height used with velocity-integral to provide volumetric flow data, including cardiac output, from 'nomogram' calculation	same
System Components	CardioQ-EDM Monitor	Components updated
	Power cord	same

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM	**Deltex CardioQ, K031706**
	Patient Interface Cable no probe included	same probe included
Mode of operation	Continuous	same
Ultrasonic clutter rejection	450 Hz & 900 Hz high-pass filters	same
Spectral Display	512 point. Fast Fourier Transform Temporal resolution 6 ms	same same
Velocity spectrum display time range (x-axis)	Full screen: 4.3 seconds Split screen: 1.4 seconds	Full screen: 3.6 seconds same
Velocity display scales (y-axis)	50, 100, 200 cm/s 250 cm/s	same not available
Doppler audio confirmation	Yes	same
Display	Color 10.4" TFT LCD screen (800 x 600 pixels) SVGA	same, but (640 x 480 pixels)
Ranges of directly measured parameters *not displayed (see FTc below)	Peak Velocity (PV) 10 – 250 cm/s Heart Rate (HR) 20 – 360 bpm Flow time (systolic) (FT)* 42 – 1500 ms Flow time to peak (FTp) 6 – 750 ms Stroke Distance (SD) 0.2 – 165 cm Mean Acceleration (MA) 0.1 – 366 m/s^2	Peak Velocity (PV) 10 – 220 cm/s same same same same same
Ranges of calculated parameters	Stroke Volume (SV) 0 – 999 ml Cardiac Output (CO) 0 - 99.9 L/min	same same

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM	**Deltex CardioQ, K031706**
	Corrected Flow Time (FTc) 24 – 999 ms	same
	Minute Distance (MD) 4 – 59400 cm	same
	Cardiac Index (CI) 0 – 99.9 L/min/m^2	same
	Stroke Volume Index (SVI) 0 – 99.9 L/m^2	same
	Systemic Vascular Resistance (SVR) 0 – 9999 dyne.sec/cm^{-5}	
	Systemic Vascular Resistance Index (SVRI) 0 – 999 dyne.sec/cm^{-5}	
Operating modes	Patient Data entry	same
	Probe Focus	same
	Run Mode	same
Controls & user interface	Control knob (function dependent on screen)	same
	Audio volume knob 6 'soft' buttons (function dependent on screen)	same
Parameters displayed	Eight of the following can be displayed above the spectral display (access to all with split screen):	Six of the following can be displayed above the spectral display (access to all with split screen):
	Peak Velocity (PV)	same
	Heart Rate (HR)	same
	Stroke Distance (SD)	same
	Mean Acceleration (MA)	same
	Stroke Volume (SV)	same
	Cardiac Output (CO)	same
	Minute Distance (MD)	same
	Corrected Flow Time (FTc)	same
	Flow Time to peak (FTp)	same
	Cardiac Index (CI)	same
	Stroke Volume Index (SVI)	same

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM	**Deltex CardioQ, K031706**
	Systemic Vascular Resistance (SVR) Systemic Vascular Resistance Index (SVRI)	same same
Parameters update rate	Every 1 to 20 heart beats	same
Trend history	Up to 240 hours/Unlimited	Up to 48 hours
Trend temporal resolution	30 seconds	same
Accessories	Roll Stand Roll Stand Interface Kit Probes and Probe accessories: Deltex Medical 240 Hour Esophageal Doppler Probe (DP240) Deltex Medical 6 hour Esophageal Doppler Probe (I_2S) Deltex Medical 24 hour Esophageal Doppler Probe (I_2P) Deltex Medical 72 hour Esophageal Doppler Probe (I_2C)	CardioQ Pole Clamp CardioQ Probe Holder Screenshot Utility Package

Summary of Clinical and Non-Clinical Data:

Electrical safety and Electromagnetic Compatibility:

Testing has been conducted following IEC 60601 series of standards, which are FDA recognized voluntary consensus standards.

Acoustic Output Testing:

Testing has been conducted following NEMA UD 2, which is a recognized voluntary consensus standard.

Bench Testing:

Comparative bench testing of the CardioQ-EDM Cardiac Function and Fluid Status Monitoring System, using a CardioQ Cardiac Output and Fluid Status Monitoring System K031706, is included. This concludes that the two systems have substantially equivalent performance.

Animal Testing:

No animal testing is included.

Clinical Testing:

No clinical testing is included

Conclusion:

From a review of the non-clinical and clinical data, Deltex Medical Limited concludes that the CardioQ EDM is substantially equivalent in terms of safety, effectiveness and performance to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 20 2011

Deltex Medical Ltd
c/o Lawrence Brookfield
Regulatory Affairs Manager
Terminus Road
Chichester
West Sussex, PO19 8TX, United Kingdom

Re: K111542
Trade/Device Name: CardioQ-EDM Esophageal Doppler Monitor
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW, DPT, DSA
Dated: September 19, 2011
Received: September 20, 2011

Dear Mr. Brookfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.1.5 Indications for Use Statement

Indications for Use

510(k) Number (if known): K 111542

Device Name: CardioQ-EDM

Indications For Use:

The CardioQ-EDM cardiac function and fluid status monitoring system is designed to provide clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters. The CardioQ-EDM's beat-to-beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious sedated patients in the operating room, intensive care unit, emergency room or ward.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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